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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,019	12/12/2003	Qiong Cheng	CL2029USNA	2505

23906 7590 10/19/2006

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EXAMINER

KETTER, JAMES S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/735,019		CHENG ET AL.	
	Examiner		Art Unit	
	James S. Ketter		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 1-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>(3)</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of the group of mutation combinations where thrS mutation must be present, in the reply filed on 14 August 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). To clarify the restriction, it was intended that a mutant gene be elected and that all combinations of that mutant with mutants in any or all of the other four recited genes thus would be elected, as well. Thus, the election as made by Applicants is as intended.

Claims 1-12 are objected to because of the following informalities:

1) The instant claims contain non-elected subject matter, the election having been made without traverse in the reply filed on 14 August 2006.

2) Claim 4, line 2, recites "is comprises". It would appear that only 'comprises' was intended.

3) Claim 6, at line 2, has "*and*" in italics, which would not appear to have been intended.

Appropriate correction is required.

Claims 7-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 7-9 each depend from any of claims 1-3, but recite limitations to the bacterial host strain that are broader than those in claims 2 and 3, which are limited to E. coli.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (A, newly cited)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claim 1 is drawn to a bacterial production host comprising a plasmid with a target gene to be expressed and a replicon controlled by antisense regulation, and also comprising a mutation in thrS gene of the recited sequence. Claim 2 recites that E. coli is the host cell. Claim 3, while ambiguous (see the rejection, below, under 35 USC 112, second paragraph), can be interpreted as further specifying that thrS has the recited mutation. Claim 4 further specifies that the replicon is from p15A or pMB1. Claim 5 specifies that the polypeptide encoded by the target gene is useful in the production of, among others, carotenoids. Claim 6 specifies that the target gene is crtE, crtB, crtI, crtY, crtX or crtZ. Claim 7 specifies a host cell which is, among others, Pantoea. Claim 8 specifies that the host is an enteric bacterium. Claim 9 specifies that Escherichia or

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Salmonella is the host. Claim 10 is drawn to a method of expressing the target gene by growing a host cell as set forth in any of claims 1-3. Claim 11 further specifies that the polypeptide encoded by the target gene is useful in the production of, among others, carotenoids. Claim 12 specifies that the target gene is crtE, crtB, crtI, crtY, crtX or crtZ.

Cheng et al. teaches, e.g., at the Abstract, where genes of the lower carotenoid pathway reside on a plasmid having either a p15A or pMB1 replicon, mutations in, among others, thrS were found effective. At paragraphs [0016]-[0024], Cheng et al. teaches a carotenoid overproducing *E. coli* comprising a lower isoprenoid enzymatic biosynthetic pathway comprising the genes crtE, crtB, crtI, and crtY, and a mutation in the thrS gene as set forth in SEQ ID NO: 35, wherein the genes of the lower isoprenoid enzymatic biosynthetic pathway reside on an autonomously replicating plasmid comprising a replicon selected from the group consisting of p15A and pMB1. Also taught is a method for the production of a carotenoid comprising growing the carotenoid overproducing microorganism for a time sufficient to produce a carotenoid, e.g., by expressing the gene from the isoprenoid enzymatic pathway. At paragraph [0058], *E. coli* is taught as the host cell. At, e.g., Table 1, another host cell, Pantoea, is taught.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, and therefore claims 4-12 which depend therefrom, is drafted as a bacterial host of claim 2 comprising the recited plasmid of “a)” and the mutation of “b)”. However, those features are already present in claim 2. Thus, it is not clear if there is one plasmid and the one or mutations set forth in claim 1, or if there are two plasmids and two groups of mutations. While the former appears to have been intended, the claim is drafted ambiguously.

Similarly, claim 10 recites the host of any of claims 1-3 “comprising a target gene to be expressed”. However, this second recitation of the presence of a target gene makes unclear if a second target gene must be present in the cell. While only one target gene appears to have been intended, the claim is drafted ambiguously.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
14 October 2006



JAMES KETTER
PRIMARY EXAMINER